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FEB 25 2005

TECH CENTER 1600/2900

PATENT  
Docket No.: 1662/49502

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : SINGER ET AL.  
SERIAL NO. : 09/552,485  
FILING DATE : April 18, 2000  
FOR : NOVEL SYNTHESIS AND CRYSTALLIZATION OF  
PIPERAZINE RING-CONTAINING COMPOUNDS  
GROUP ART UNIT : 1624  
EXAMINER : K. Habte  
CUSTOMER NO.: 23838

PETITION UNDER 37 CFR § 1.181

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants hereby petition the Office to correct the official record in PAIR and to send us an official communication granting the benefit of Provisional Application No. 60/182,745 in the above identified application, 09/552,485. Attached are copies of a Request for Continued Examination and an Amendment accompanying the RCE filed on August 13, 2002 in 09/552,485 (also attached is a copy of a postcard receipt proving that the Office did receive the RCE and Amendment on August 13, 2002). The Office Action mailed August 26, 2002 also acknowledged having received the documents applicants filed on August 13, 2002. In the Amendment of August 13, 2002, applicants amended the first sentence of the specification to read "This application claims the benefit of U.S. Provisional Application Serial No. 60/130,047,

filed April 19, 1999 and U.S. Provisional Application Serial No. 60/182,745 filed February 16, 2000."

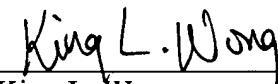
Since 09/552,485 was filed within 12 months of the filing of 60/182,745, the requirements of 35 U.S.C. 119(e) were met concerning the claiming of the benefit of 60/182,745. In addition, the requirements of 37 CFR 1.78(a)(4), in effect when 09/552,485 was filed on April 18, 2000, were also met by the Amendment filed on August 13, 2002 concerning amending the specification to claim the benefit of 60/182,745. Thus, the benefit of 60/182,745 should be accorded to 09/552,485.

Also attached is a copy of a Corrected Filing Receipt in a CIP application, 10/206,344, of 09/552,485 showing that 09/552,485 claims the benefit of 60/130,047 and 60/182,745.

Since the instant Petition is necessitated by an error on the part of the Office, no fees are believed due. However, the Commissioner is authorized to charge any fees that may be required in relation to this Petition to Deposit Account 11-0600, referencing Attorney Docket No. 01662/49502.

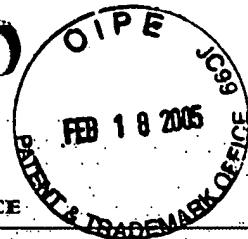
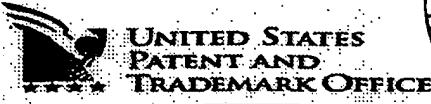
Respectfully submitted,

Date: February 18, 2005

  
\_\_\_\_\_  
King L. Wong  
Registration No. 37,500

Attachments

KENYON & KENYON  
1500 K Street, N.W., Suite 700  
Washington, D.C. 20005-1257  
Tel.: (202) 220-4200



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Page 1 of 2

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Commissioner for Patents  
Washington, DC 20231  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
10/206,344	07/29/2002	1624	740	1662/49504	0	13	2

CONFIRMATION NO. 1562

CORRECTED FILING RECEIPT



\*OC000000008903211\*

Date Mailed: 10/03/2002

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

**Applicant(s)**

Claude Singer, Kfar Saba, ISRAEL;  
Anita Liberman, Tel Aviv, ISRAEL;  
Nina Finkelstein, Herzliya, ISRAEL;

**Domestic Priority data as claimed by applicant**

This application is a CIP of 09/552,485 04/18/2000  
which claims benefit of 60/130,047 04/19/1999  
and claims benefit of 60/182,745 02/16/2000

**Foreign Applications****If Required, Foreign Filing License Granted 08/30/2002****Projected Publication Date: 12/12/2002****Non-Publication Request: No****Early Publication Request: No****Title**

Novel synthesis and crystallization of piperazine ring-containing compounds

10/7/02

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The stamp of the Patent Office hereon may be taken as acknowledging  
receipt, on the date stamped, of

INVENTOR(S): SINGER ET AL.

SERIAL NO.: 09/552,485

FILED: April 18, 2000

TITLE: NOVEL SYNTHESIS AND CRYSTALLIZATION OF  
PIPERAZINE RING-CONTAINING COMPOUNDS

GROUP ART UNIT: 1624

The PTO is authorized to charge any fees associated with this filing to  
Deposit Account No. 11-0600

PAPERS FILED:

**Fee Transmittal, Request for Continued Examination  
(RCE) and Amendment.**

WDW:bcl

August 13, 2002

1662/49502

DC01 399312 v 1



**REQUEST  
FOR  
CONTINUED EXAMINATION (RCE)  
TRANSMITTAL**

Subsection (b) of 35 U.S.C. § 132, effective on May 29, 2000, provides for continued examination of an utility or plant application filed on or after June 8, 1995. See The American Inventors Protection Act of 1999 (AIPA).

<i>TECH CENTER 1600/2900</i>	<i>FEB 18 2005</i>
<i>Application Number</i>	09/552,485
<i>Filing Date</i>	April 18, 2000
<i>Examiner Name</i>	K. HABTE
<i>First Named Inventor</i>	SINGER ET AL.
<i>Group Art Unit</i>	1624
<i>Attorney Docket Number</i>	1662/49502

This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application.

**NOTE:** 37 C.F.R. § 1.114 is effective on May 29, 2000. If the above-identified application was filed prior to May 29, 2000, applicant may wish to consider filing a continued prosecution application (CPA) under 37 C.F.R. § 1.53 (d) (PTO/SB/29) instead of a RCE to be eligible for the patent term adjustment provisions of the AIPA. See Changes to Application Examination and Provisional Application Practice, Interim Rule, 65 Fed. Reg. 14865 (Mar. 20, 2000), 1233 Off. Gaz. Pat. Office 47 (Apr. 11, 2000), which established RCE practice.

1. Submission required under 37 C.F.R. § 1.114

a.  Previously submitted

- i. Consider the amendment(s)/reply under 37 C.F.R. § 1.116 previously filed on **July 10, 2002**.  
(Any unentered amendment(s) referred to above will be entered).

- ii.  Consider the arguments in the Appeal Brief or Reply Brief previously filed on  
 Other

b. Enclosed

- i.  Amendment/Reply  
ii.  Affidavit(s)/Declaration(s)  
iii.  Information Disclosure Statement (IDS)  
iv.  Other

This application claims the benefit of U.S. Provisional Application Serial No. 60/130,047, filed April 19, 1999; and U.S. Provisional Application Serial No. 60/182,745, filed February 16, 2000.

2. Miscellaneous

- a.  Suspension of action on the above-identified application is requested under 37 C.F.R. § 1.103(c) for a period of \_\_\_\_\_ months. (Period of suspension shall not exceed 3 months; Fee under 37 C.F.R. § 1.17(i) required)

- b.  Other

3. Fees The RCE fee under 37 C.F.R. § 1.17(e) is required by 37 C.F.R. § 1.114 when the RCE is filed.

- a.  The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No.11-0600

- i.  RCE fee required under 37 C.F.R. § 1.17(e)  
ii.  Extension of time fee (37 C.F.R. §§ 1.136 and 1.17)  
iii.  Other  
iv.  Charge any additional fees under 37 C.F.R. § 1.16 and 1.17

- b.  Check in the amount of \$ \_\_\_\_\_ enclosed

- c.  Payment by credit card (Form PTO-2038 enclosed)

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED**

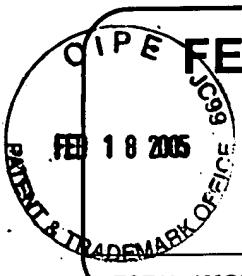
Name (Print /Type)	W. David Wallace	Registration No. (Attorney/Agent)	42,210
Signature	<i>W. David Wallace</i>	Date	August 13, 2002

**CERTIFICATE OF MAILING OR TRANSMISSION**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, Box RCE, Washington, DC 20231, or facsimile transmitted to the U.S. Patent and Trademark Office on:

Name (Print /Type)			
Signature		Date	

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND Fees and Completed Forms to the following address: Commissioner for Patents, Box RCE, Washington, DC 20231.



# FEE TRANSMITTAL for FY 2002

Patent fees are subject to annual revision.

<b>TOTAL AMOUNT OF PAYMENT</b>	(\$)	1,140.00
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Complete If Known

Application Number	09/552,485
Filing Date	April 18, 2000
First Named Inventor	Singer et al.
Examiner Name	K. Habte
Group / Art Unit	1624
Attorney Docket No.	1662/4950

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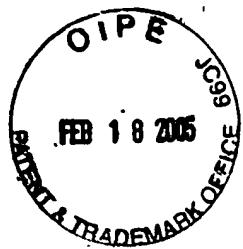
METHOD OF PAYMENT (check one)					FEE CALCULATION (continued)					
<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:										
Deposit Account Number		11-0600			Fee Code		Large Entity Fee (\$)	Small Entity Fee (\$)	Fee Description	Fee Paid
Deposit Account Name		KENYON & KENYON			105		130	205	65 Surcharge - late filing fee or oath	
<input checked="" type="checkbox"/> Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17 <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27					127		50	227	25 Surcharge - late provisional filing fee or cover sheet.	
<input type="checkbox"/> Payment Enclosed: <input type="checkbox"/> Check <input type="checkbox"/> Credit card <input type="checkbox"/> Money Order <input type="checkbox"/> Other					139		130	139	130 Non-English specification	
					147		2,520	147	2,520 For filing a request for reexamination	
					112		920*	112	920* Requesting publication of SIR prior to Examiner action	
					113		1,840*	113	1,840* Requesting publication of SIR after Examiner action	
					115		110	215	55 Extension for reply within first month	
					116		400	216	200 Extension for reply within second month	400.00
					117		920	217	460 Extension for reply within third month	
					118		1,440	218	720 Extension for reply within fourth month	
					128		1,960	228	980 Extension for reply within fifth month	
					119		320	219	160 Notice of Appeal	
					120		320	220	160 Filing a brief in support of an appeal	
					121		280	221	140 Request for oral hearing	
					138		1,510	138	1,510 Petition to institute a public use proceeding	
					140		110	240	55 Petition to revive – unavoidable	
					141		1,280	241	640 Petition to revive – unintentional	
					142		1,280	242	640 Utility issue fee (or reissue)	
					143		460	243	230 Design issue fee	
					144		620	244	310 Plant issue fee	
					122		130	122	130 Petitions to the Commissioner	
					123		50	123	50 Processing fee under 37 CFR 1.17 (q)	
					126		180	126	180 Submission of Information Disclosure Stmt	
					581		40	581	40 Recording each patent assignment per property (times number of properties)	
					146		740	246	370 Filing a submission after final rejection (37 CFR § 1.129(a))	
					149		740	249	370 For each additional invention to be examined (37 CFR § 1.129(b))	
					179		740	279	370 Request for Continued Examination (RCE)	740.00
					169		900	169	900 Request for expedited examination of a design application	
					Other fee (specify)					
					*Reduced by Basic Filing Fee Paid					SUBTOTAL (3) (\$1,140.00)

\*\*or number previously paid, if greater; For Reissues, see above

SUBMITTED BY				Complete (if applicable)	
Name (Print/Type)	W. David Wallace	Registration No. Attorney/Agent)	42,210	Telephone	202.220.4200
Signature				Date	August 13, 2002

**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**Burden Hour Statement:** This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



PATENT  
Docket No.: 1662/49502

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT : SINGER ET AL.  
SERIAL NO. : 09/552,485  
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PIPERAZINE RING-CONTAINING COMPOUNDS  
GROUP ART UNIT : 1624  
EXAMINER : K. Habte

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**Amendment**

ASSISTANT COMMISSIONER FOR  
PATENTS AND TRADEMARKS  
Washington, D.C. 20231

Sir:

A Request for Continued Examination has been filed concurrently herewith. Applicants respectfully request reconsideration of the above-identified application in view of the following amendments and remarks. Applicants enclose the fee for a two-month extension of time; however, the Commissioner is authorized to charge or debit any underpayment or overpayment to Deposit Account 11-0600.

**IN THE SPECIFICATION:**

On page 1, please substitute the following paragraph for paragraph 1:

-- This application claims the benefit of U.S. provisional Application Serial No. 60/130,047, filed April 19, 1999, and U.S. provisional Application Serial No. 60/182,745, filed February 16, 2000.--

**IN THE CLAIMS:**

Please cancel claims 29, 36, and 42-45 without prejudice or disclaimer.

Please amend claims 30, 31, 37, 38 and 41 as follows:

30. (Amended) A crystalline adduct of mirtazapine and water containing up to about three weight percent water.
31. (Amended) The adduct of mirtazapine and water of claim 30 prepared by precipitation from a solvent comprising water and either an alcohol or acetone.
37. (Amended) A crystallized adduct of mirtazapine and water prepared by:
  - i) crystallizing mirtazapine from a solution comprising water;
  - ii) recovering crystallized mirtazapine; and
  - iii) drying the crystallized mirtazapine until the crystallized mirtazapine contains up to about 3 percent water.
38. (Amended) The adduct of mirtazapine and water of claim 37 wherein the solution also comprises an alcohol.
41. (Amended) The adduct of mirtazapine and water of claim 40 wherein the solution comprises a ratio of ethanol:water ranging from about 1:1 to about 1:4.

Please add new claims 46-53 as follows:

46. (New) A process for preparing crystallized mirtazapine comprising the steps of:
  - i) dissolving mirtazapine in an organic solvent, thereby forming a solution;
  - ii) adding water to the solution;
  - iii) precipitating mirtazapine; and
  - iv) drying the precipitated mirtazapine under conditions sufficient to produce crystallized mirtazapine having up to about 3% by weight water.
47. (New) The process of claim 46, wherein the organic solvent is selected from the group consisting of methanol, ethanol, and isopropyl alcohol.
48. (New) The process of claim 46, wherein the drying conditions comprise elevated temperature and reduced pressure.

49. (New) The process of claim 48, wherein the elevated temperature is about the reflux temperature of the organic solvent.
50. (New) The process of claim 46, wherein the dissolving step comprises refluxing the organic solvent.
51. (New) The process of claim 46, wherein the adding step comprises adding water dropwise to the solution.
52. (New) The process of claim 46, wherein the precipitating step comprises cooling the solution to about 10 °C.
53. (New) The process of claim 47,  
wherein the dissolving step comprises refluxing the organic solvent;  
wherein the adding step comprises adding water dropwise to the solution;  
wherein the precipitating step comprises cooling the solution to about 10 °C; and  
wherein the drying conditions comprise heating the precipitated mirtazapine to the reflux temperature of the organic solvent under reduced pressure.

#### REMARKS

The foregoing claim amendments were not entered when submitted on July 11, 2002, under 37 CFR § 1.116. Therefore, claims 29-45 are currently pending in the application. Entry of the foregoing amendments is respectfully requested. Upon entry of the amendments, claims 30-35, 37-41, and 46-53 will be pending.

Applicants have also amended the specification to add a claim of priority to a second provisional application.

Applicants' undersigned attorney will contact the Examiner shortly to request and arrange an interview.

In view of the foregoing amendments and the remarks of record, Applicants respectfully request allowance of the pending claims. The Examiner is invited to contact the undersigned attorney regarding any matter concerning the pending application.

Respectfully submitted,

Date: 8/13/02



W. David Wallace  
Registration No. 42,210

KENYON & KENYON  
1500 K Street, N.W., Suite 700  
Washington, D.C. 20005-1257  
Tel.: (202) 220-4200  
Fax.: (202) 220-4201

## MARKED-UP VERSION OF AMENDMENTS

### IN THE SPECIFICATION:

This application claims the benefit of U.S. provisional Application Serial No. 60/130,047, filed April 19, 1999, and U.S. provisional Application Serial No. 60/182,745, filed February 16, 2000.

### IN THE CLAIMS:

30. [The] A crystalline adduct of mirtazapine and water [of claim 29] containing up to about three weight percent water.
31. [An] The adduct of mirtazapine and water of claim 30 prepared by precipitation from a solvent comprising water and either an alcohol or acetone.
37. A[n] crystallized adduct of mirtazapine and water prepared by:
  - [1. slow addition of water at elevated temperature to a mixture of mirtazapine and an organic solvent selected from the group consisting of alcohols and acetone,
  2. precipitating the adduct by cooling, and
  3. separating the adduct from the water and organic solvent.]
    - i) crystallizing mirtazapine from a solution comprising water;
    - ii) recovering crystallized mirtazapine; and
    - iii) drying the crystallized mirtazapine until the crystallized mirtazapine contains up to about 3 percent water.
38. The adduct of mirtazapine and water of claim 37 wherein the [organic solvent is] solution also comprises an alcohol.
41. The adduct of mirtazapine and water of claim 40 wherein [from about one to about four volumes of water are added relative to the amount of ethanol] the solution comprises a ratio of ethanol:water ranging from about 1:1 to about 1:4.